REMARKS

Summary of the Office Action

Claims 1-4, and 7 have been rejected under 35 USC 103(a) as allegedly obvious over U.S. Patent No. 6,264,625 to Rubenstein et al. ("*Rubenstein*").

Claims 5 and 6 have been rejected 35 USC 103(a) as allegedly obvious over *Rubenstein* in view of U.S. Patent No. 5,947,911 to Wong et al. ("*Wong*").

Claims 33 and 35 have been rejected under 35 USC 103(a) as allegedly obvious over *Rubenstein* in view of U.S. Patent No. 5,575,770 to Melsky et al. ("*Melsky*").

Response to the Office Action

A. Claims 1-4 and 7

Claims 1-7 and 12-35 are pending in the application. Claims 12-32 and 34 have been withdrawn from examination, claims 1, 5, 6, and 33 have been amended herein, and new claims 36-37 have been added. Therefore, upon entry of the present amendment, claims 1-7, 33 and 35-37 will be subject to examination.

Claim 1-4 and 7 are not obvious over *Rubenstein* at least because *Rubenstein* fails to teach or suggest that "the system includes one or more anti-infective coatings disposed on a surface of the pump."

The Examiner has admitted that *Rubenstein* does not disclose the above limitation but has argued that such limitation is obvious in view of *Rubenstein's* teaching of the need for bacteria and other infective agents in the cerebrospinal fluid (CSF) to be neutralized prior to fluid transfer. The Examiner has further argued in the Advisory Action of 11/20/2007 that even if *Rubenstein* teaches that the antibodies are present in order to purify the fluid, this has the same effect of preventing infections. Applicant respectfully submits that the Examiner may have misapprehended *Rubenstein*.

Rubenstein teaches the use of antibodies at col. 9, lines 47-48, which reads:

> The inner wall of the portion of container 52 that forms chamber 56 may be coated with antibodies specific to particular agents present in the cerebrospinal fluid *(sic)* That is, the antibodies may be linked or bound to the inner wall of chamber 56 so that they may capture putative toxic chemicals and draw them out of solution, keeping the driving

> concentration gradient between cerebrospinal fluid and dialysate high. Alternatively, the antibodies may be bound to beads, strands or other structures which may be periodically introduced into and retrieved from the dialysate chamber through dialysate port 60.

The above description – which is the only portion of *Rubenstein* discussing the use of antibodies - relates to FIG. 9, which shows that CSF flows into a container 52 where toxic or putative chemicals that are present in the CSF are transferred into a dialysate by diffusing through a micro-porous membrane. Such diffusion is a function of the toxic chemical concentration gradient existing between the CSF and the dialysate. Therefore, the antibodies of *Rubenstein* are not present anywhere in the pump, contrary to the invention claimed by Applicant, and further are not intended to inhibit the spread of infections, also contrary to the invention claimed by Applicant, but instead are intended to purify the CSF prior to recycling into the patient's brain. Applicant submits that such distinction makes Applicant's claimed invention patentably distinguishable from *Rubenstein*, because Applicant's research has determined that infections following implantation of fluid management systems in a patient are often caused by bacteria that adhere to the pump walls and that not only cause danger and inconvenience to the patient, but that also compromise long term use of the fluid management system by the patient. Once established, such bacteria are very resistant to treatment and extremely difficult to remove, so that antibiotic concentrations may be required that are up to 100 times the amounts required to kill the same bacteria in free condition.

More particularly, *Rubenstein* defines "putative toxic chemicals" as "deleterious materials in the patient's cerebrospinal fluid, such as neurotoxic substances and substances associated with histologic lesions." Applicant cannot find anywhere in *Rubenstein* a teaching directed to inhibiting infections, and submits that the Examiner's argument of equivalency between the filtering of toxic chemicals in *Rubenstein* and infection prevention in Applicant's claims is unsupported by *Rubenstein* and is based on impermissible hindsight.

Applicant further submits that the Examiner's argument of equivalency between Applicant's provision of anti-infective agents in the pump, rather than in *Rubenstein's* separate reservoir, is also based on impermissible hindsight. *Rubenstein* clearly shows in FIG. 9 the use of a pump but has defined his invention as providing antibodies in a dedicated reservoir rather than in the pump, without even discussing coating the pump with anti-infective agents and

contradicting an argument that providing anti-infective agents in the pump is obvious in view of providing filtering antibodies in a reservoir.

For at least these reasons, claim 1 and the claims depending therefrom are not obvious in view of the prior art of record.

B. Claims 5-6

Rubenstein has been discussed above. Claims 5-6 are not obvious over *Rubenstein* in view of *Wong* also because those references, alone or in combination, do not teach or suggest the limitation "wherein the chemical composition is detected by an implanted sensor."

Rubenstein does not teach the use of chemical sensors, as the Examiner has admitted, and *Wong* teaches the use of a blood analyzer disposed outside of the patient's body, therefore, not "implanted."

C. Claim 33

Rubenstein has been discussed above. Claim 33 is not obvious over *Rubenstein* in view of *Melsky* also because those two references, alone or in combination, do not teach or suggest the limitation "wherein the anchors are selected from the group consisting of barbed insertion pins, a screw threading defined on an outside surface of the pump, staples, adhesive compounds, one or more pins designed to be inserted into the abdominal wall, and combinations thereof."

Rubenstein does not teach the use of anchoring means, as the Examiner has admitted, and *Melsky* teaches the use of rings extending from the pump and stitched to adjacent body tissue, therefore, not anchored as recited in claim 33.

D. Claim 35

Rubenstein has been discussed above. Claim 35 is not obvious over *Rubenstein* in view of *Melsky* also because those two references, alone or in combination, do not teach or suggest the limitation "wherein the housing comprises a material promoting fibrotic ingrowth into the housing."

Applicant was unable to find teachings in *Melsky* related to the use of biocompatible materials or materials promoting fibrotic ingrowth. Applicant found teachings in *Rubenstein* related to the use of biocompatible materials, with the examples cited by *Rubenstein* being stainless steel, a relatively inert polymer such as polytetrafluoroethylene, and silicone. Applicant disputes that the cited references teach that such materials "promote" fibrotic ingrowth.

The Examiner has argued in the Advisory Action that "promotes fibrotic ingrowth" means that the material allows fibrotic ingrowth to take place and does not contain additives that prevent ingrowth. Applicant submits that the Examiner may have misapprehended the meaning of "promote."

The American Heritage Dictionary, 4th ed. (2000) defines "promote" as "to contribute to the progress or growth of; further," and Merriam-Webster Online defines "promote" as "to contribute to the growth or prosperity of: further." Therefore, both of the above cited dictionaries define "promote" as more than "not prevent," and, based on such definitions, none of the prior art of record teaches the use of materials that "promote" fibrotic ingrowth.

More particularly, PTFE and silicone, taught by *Rubenstein*, do not "contribute to the progress or growth of fibrotic ingrowth." For example, it is well known that PTFE has very strong anti-adhesion properties.

Applicant fails to understand the Examiner's comment in the Advisory Action that "applicant does not actually claim that fibrotic ingrowth occurs." The meaning of "promote" has been discussed above, and claims 34 and 35 are directed to a system for achieving a certain result, not to the result itself.

For at least the above reasons, the removal of all rejections of claims 1-7, 33 and 35 is respectfully requested.

E. Claims 36 and 37

New claims 36 and 37 are directed to the disposition of the coating on the pump, more particularly, on the housing, and to the type of coating selected, namely, a coating that prevents adhesion of bacteria to the pump. New claims 36 and 37 are fully supported in the specification.

Conclusion

In view of the foregoing amendments and remarks, it is respectfully submitted that the application is now in condition for allowance. A notice to that effect is respectfully requested.

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Respectfully submitted,

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